Complete Summary

GUIDELINE TITLE

Analgesia and anesthesia for the breastfeeding mother.

BIBLIOGRAPHIC SOURCE(S)

Montgomery A, Hale TW, Academy of Breastfeeding Medicine Protocol Committee. ABM clinical protocol #15: analgesia and anesthesia for the breastfeeding mother. Breastfeed Med 2006 Winter;1(4):271-7. [50 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Infant health/nutrition
- Conditions that require analgesia and anesthesia for the breastfeeding mother

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Anesthesiology
Cardiology
Critical Care
Dentistry
Family Practice
Gastroenterology
Internal Medicine
Neurological Surgery
Nursing
Nutrition
Obstetrics and Gynecology
Pediatrics
Plastic Surgery
Surgery
Thoracic Surgery

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Dentists Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for safe and appropriate use of pharmacologic agents for anesthesia and pain relief in breastfeeding women during labor and in the postpartum period and for other surgery in lactating women

TARGET POPULATION

- Women in childbirth labor with pain
- Women in the postpartum period with pain
- Breastfeeding mothers undergoing surgery

INTERVENTIONS AND PRACTICES CONSIDERED

- Informed consent discussion in prenatal period on pain management during labor
- 2. Analgesia and anesthesia for labor
 - Support by doula
 - Nonpharmacologic methods (hypnosis, psychoprophylaxis (Lamaze), intradermal or subcutaneous water injections for back pain)
 - Intravenous opiates (fentanyl, meperidine/pethidine) (Nalbuphine, butorphanol, and pentazocine in specific circumstances)
 - Epidural analgesia, including minimization of dose, conservative use of fluids, and postpartum follow-up and breastfeeding support
- 3. Anesthesia for Cesarean section (regional, general)
- 4. Postpartum anesthesia

- Nonopioid analgesics (acetaminophen, ketorolac, diclofenac, cox-2 inhibitors)
- Intravenous medications (morphine, fentanyl, nalbuphine, butorphanol, pentazocine, hydromorphone)
- Patient-controlled analgesia (PCA)
- Oral medications (hydrocodone, codeine)
- Epidural/spinal medications
 - Single-dose opioids
 - Continuous infusion
- 5. Anesthesia for surgery in breastfeeding mothers, including choice of agent and unlikely need to pump and discard breast milk
- 6. Resumption of breastfeeding following anesthesia

MAJOR OUTCOMES CONSIDERED

- Pain relief
- Adverse events in the breastfed infant associated with treatment
- Successful breastfeeding

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An initial search of relevant published articles written in English in the past 20 years in the fields of medicine, psychiatry, psychology, and basic biological science is undertaken for a particular topic. Once the articles are gathered, the papers are evaluated for scientific accuracy and significance.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I Evidence obtained from at least one properly randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports; or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

An expert panel is identified and appointed to develop a draft protocol using evidence based methodology. An annotated bibliography (literature review), including salient gaps in the literature, are submitted by the expert panel to the Protocol Committee.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Draft protocol is peer reviewed by individuals outside of lead author/expert panel, including specific review for international applicability. Protocol Committee's sub-

group of international experts recommends appropriate international reviewers. Chair (co-chairs) institutes and facilitates process. Reviews submitted to committee Chair (co-chairs).

Draft protocol is submitted to The Academy of Breastfeeding Medicine (ABM) Board for review and approval. Comments for revision will be accepted for three weeks following submission. Chair (co-chairs) and protocol author(s) amends protocol as needed.

Following all revisions, protocol has final review by original author(s) to make final suggestions and ascertain whether to maintain lead authorship.

Final protocol is submitted to the Board of Directors of ABM for approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Analgesia and Anesthesia for Labor

Maternity care providers should initiate an informed consent discussion for pain management in labor during the prenatal period before the onset of labor. Risk discussion should include what is known about the effects of various modalities on the progress of labor, risk of instrumented and Cesarean delivery, effect on the newborn, and possible breastfeeding effects.

Continuous support in labor, ideally by a trained doula, reduces the need for pharmacologic pain management in labor, decreases instrumented delivery and Cesarean section, and leads to improved breastfeeding outcomes both in the immediate postpartum period and several weeks after birth (Hodnett et al., 2003).

Nonpharmacologic methods for pain management in labor such as hypnosis, psychoprophylaxis (e.g., Lamaze), intradermal or subcutaneous water injections for back pain, and so on, appear to be safe, have no known adverse neonatal effects, and may reduce the need for pharmacologic pain management. More study of breastfeeding outcomes is needed for these modalities.

Intravenous Opiates

- 1. Shorter-acting opiates such as fentanyl are preferred. Remifentanil is potent and has rapid onset and offset but can be associated with a high incidence of maternal apnea, requiring increased monitoring. Its transfer *in utero* to the fetus is minimal.
- 2. Meperidine/pethidine generally should not be used except in small doses less than 1 hour before anticipated delivery because of greater incidence and duration of neonatal depression, cyanosis, and bradycardia.
- 3. Nalbuphine, butorphanol, and pentazocine may be used for patients with certain opioid allergies or at increased risk of difficult airway management or respiratory depression. However, these medications may interfere with fetal

- heart rate monitoring interpretation. Observe the mother and infant for psychotomimetic reactions (3%).
- 4. Multiple doses of intravenous analgesic, and their timing of administration may lead to greater neonatal effects. For example, fentanyl administration within 1 hour of delivery or meperidine administration between 1 and 4 hours before delivery is associated with more profound neonatal effects.
- 5. When a mother has received intravenous narcotics for labor, mother and baby should be given more skin-to-skin time to encourage early breastfeeding (Nissen et al., 1995).

Epidural Analgesia

- If epidural anesthesia is chosen, methods that minimize the dose of medication and minimize motor block should be used. Longer durations of epidural analgesia should be avoided if possible (Rosen & Lawrence, 1994), and administration should be delayed until necessary to minimize effect on labor outcomes that may secondarily affect breastfeeding. Combined spinalepidural analgesia and patient-controlled epidural analgesia may be preferable.
- 2. Infants lose more weight in the first postpartum days when labor medications are used (Dewey et al., 2003). Some of this weight loss may be a result of mothers receiving an intravenous (IV) fluid load for epidural analgesia. One report notes babies are slightly heavier on average and lose more weight in the first days postpartum when epidural analgesia is used (Merry & Montgomery, 2000). In addition, the use of large volumes of intrapartum IV fluids has been associated with a decrease in plasma oncotic pressure (Cotterman, 2004), which may then increase breast engorgement and interfere with subsequent milk production and/or transfer. Conservative use of fluids may mitigate this effect. Definitive studies of these interrelationships are needed in order to better assess first-week weight loss in individual newborns.
- 3. When epidural analgesia has been used for labor, particular care to provide mothers with good breastfeeding support and close follow-up after postpartum hospitalization should be taken.

Anesthesia for Cesarean Section

Regional anesthesia (epidural or intrathecal/spinal) is preferred over general anesthesia. (Krishnan, Gunaskearan, & Bhaskaranan, 1995; Kangas-Saarel, et al., 1989)

Separation of the mother and baby should be minimized and breastfeeding initiated as soon as feasible. In fact, the baby may go to the breast in the operating room during abdominal closure with assistance to support the infant on the mother's chest. If breastfeeding is initiated in the recovery room, there is the added advantage that the incision is often still under the influence of the anesthetic.

A mother may breastfeed postoperatively as soon as she is alert enough to hold the baby.

Postpartum Anesthesia

Nonopioid Analgesics

Nonopioid analgesics generally should be the first choice for pain management in breastfeeding postpartum women, as they do not impact maternal or infant alertness.

- 1. Acetaminophen and ibuprofen are safe and effective for analgesia in postpartum mothers.
- 2. Parenteral ketorolac may be used in mothers not subject to hemorrhage, and with no history of gastritis, aspirin allergy, or renal insufficiency.
- 3. Diclofenac suppositories are available in some countries and commonly used for postpartum analgesia. Milk levels are extremely low.
- 4. Cox-2 inhibitors such as celecoxib may have some theoretic advantages if maternal bleeding is a concern. This must be balanced with higher cost and possible cardiovascular risks, which should be minimal with short-term use in healthy young women.

Both pain and opioid analgesia can have a negative impact on breastfeeding outcomes; thus, mothers should be encouraged to control their pain with the lowest medication dose that is fully effective. Opioid analgesia postpartum may affect babies' alertness and suckling vigor. However, when maternal pain is adequately treated, breastfeeding outcomes improve (Hirose et al., 1996). Especially after Cesarean birth or severe perineal trauma requiring repair, mothers should be encouraged to adequately control their pain.

Intravenous Medications

- 1. Meperidine should be avoided because of reported neonatal sedation when given to breastfeeding mothers postpartum (Wittles, Scott, & Sinatra, 1990), in addition to the concerns of cyanosis, bradycardia, and risk of apnea, which have been noted with intrapartum administration (Hamza et al., 1992; Hodgkinson et al., 1978).
- 2. The administration of moderate to low doses of IV or intramuscular (IM) morphine is preferred as its passage to milk and oral bioavailability in the infant are least with this agent (Wittles, Scott, & Sinatra, 1990; Feilberg et al., 1989).
- 3. When patient-controlled IV analgesia (PCA) is chosen after Cesarean section, morphine or fentanyl is preferred to meperidine. (Wittles et al., 1997)
- 4. Although there are no data on the transfer of nalbuphine, butorphanol, and pentazocine into milk, there have been numerous anecdotal reports of a psychotomimetic effect when these agents are used in labor. They may be suitable in individuals with certain opioid allergies or other conditions described in the preceding section on labor.
- 5. Hydromorphone (approximately 7 to 11 times as potent as morphine) is sometimes used for extreme pain in a PCA, IM, IV, or orally. Following a 2-mg intranasal dose, levels in milk were quite low with a relative infant dose of about 0.67% (Edwards et al., 2003). This correlates with about 2.2 micrograms/day via milk. This dose is probably too low to affect a breastfeeding infant, but this is a strong opioid and some caution is recommended.

Oral Medications

1. Hydrocodone and codeine have been used worldwide in millions of breastfeeding mothers. This suggests they are suitable choices even though there are no data reporting their transfer into milk. Higher doses (10 mg hydrocodone) and frequent use may lead to some sedation in the infant.

Epidural/Spinal Medications

- 1. Single-dose opioid medications (e.g., neuraxial morphine) should have minimal effects on breastfeeding because of negligible maternal plasma levels achieved. Extremely low doses of morphine are effective.
- Continuous post-Cesarean epidural infusion may be an effective form of pain relief that minimizes opioid exposure. A randomized study that compared spinal anesthesia for elective Cesarean with or without the use of postoperative extradural continuous bupivacaine found that the continuous group had lower pain scores and a higher volume of milk fed to their infants (Hirose et al., 1996).

Anesthesia for Surgery in Breastfeeding Mothers

The implications of drugs used in anesthesia in postpartum mothers depends on numerous factors, including the age of the infant, stability of the infant, stage of lactation (early or late stage), and ability of the infant to handle the clearance of small quantities of anesthetic medications (Hale, 1999).

The ability of the infant to clear small amounts of these medications is of primary concern before returning to breastfeeding. Infants subject to apnea, hypotension, or weakness probably should be protected by a few more hours of interruption from breastfeeding before resuming (12 to 24 h) nursing.

Mothers with normal term or older infants generally can resume breastfeeding as soon as they are awake, stable, and alert. Resumption of normal mentation is a hallmark that these medications have left the plasma compartment (and thus the milk compartment) and entered adipose and muscle tissue where they are slowly released. A single pumping and discarding of the mother's milk following surgery will significantly eliminate any drug retained in milk fat, although this is seldom necessary and not generally recommended. For women who undergo postpartum tubal ligation, breastfeeding interruption is not indicated, as the volume of colostrum is small (Rathmell, Viscomi, & Ashburn, 1997). In addition, the levels of medication in the maternal plasma and milk are low once mothers resume normal mentation. Regional anesthesia is recommended for this procedure in preference to general anesthetic for maternal safety.

Mothers who have undergone dental extractions or other procedures requiring the use of single doses of medication for sedation and analgesia can breastfeed as soon as they are awake and stable. Although shorter-acting agents such as fentanyl and midazolam may be preferred, single doses of meperidine or diazepam are unlikely to affect the breastfeeding infant (Hale, 1999).

Mothers who have undergone plastic surgery, such as liposuction, in which large doses of local anesthetics (lidocaine) have been used probably should pump and discard their milk for 12 hours before resuming breastfeeding.

Specific Agents Used for Anesthesia and Analgesia

Anesthetics

Drugs used for induction such as propofol, midazolam, etomidate, or thiopental enter the milk compartment only minimally, as they have extraordinarily brief plasma distribution phases (only minutes) and hence their transport to milk is low to nil (Andersen et al., 1987; Matheson, Lunde, & Bredesen, 1990; Dailland et al., 1989; Schmitt et al., 1987).

Little or nothing has been reported about the use of anesthetic gases in breastfeeding mothers. However, they too have brief plasma distribution phases and milk levels are likely nil.

The use of ketamine in breastfeeding mothers is unreported. Because of its high rate of psychotomimetic effect, including hallucinations and dissociative anesthesia (catalepsy, nystagmus), ketamine is probably not an ideal anesthetic agent for breastfeeding mothers.

Analgesics

Opioid Analgesics

- 1. Morphine is still considered an ideal analgesic for breastfeeding mothers because of its limited transport to milk, and poor oral bioavailability in infants (Wittles, Scott, & Sinatra, 1990; Wittles et al., 1997).
- 2. The transfer of meperidine into breast milk is documented, although it is somewhat low (1.7% to 3.5% of maternal dose). However, the administration of meperidine and its metabolite (normeperidine) is consistently associated with neonatal sedation, which is dose related. Transfer into milk and neonatal sedation have been documented for up to 36 hours after the dose (Wittles, Scott & Sinatra, 1990). Meperidine should be avoided during labor and in postpartum analgesia (except, perhaps, within 1 hour before delivery). Infants of mothers who have been exposed to repeated doses of meperidine should be closely monitored for sedation, cyanosis, bradycardia, and possibly seizures.
- 3. Although there are no published data on remifentanil, this esterasemetabolized opioid has a brief half-life even in infants (<10 minutes) and has been documented to produce no fetal sedation even *in utero*. Although its duration of action is limited, it could be used safely, and indeed may be ideal in breastfeeding mothers for short painful procedures.
- 4. Fentanyl levels in breast milk have been studied and are extremely low to below the limit of detection (Leuschen, Wolf, & Rayburn, 1990; Madej & Strunin, 1987).
- 5. Sufentanil transfer into milk has not been published, but it should be similar to fentanyl.
- 6. Nalbuphine, butorphanol, and pentazocine levels in breast milk have not been published. At this time they would only be indicated in the specific situations mentioned previously. If these agents are used, observe the mother and infant for psychotomimetic reactions (3%).
- 7. Hydrocodone and codeine have been used in millions of breastfeeding mothers. Occasional cases of neonatal sedation have been documented, but

these are rare and generally dose related. Doses in breastfeeding mothers should be kept at the minimum necessary to control pain. Routine, consistent dosing throughout the day may lead to sedative effects in the breastfed infant.

Non-Steroidal Anti-inflammatory Analgesics

- 1. Ibuprofen is considered an ideal, moderately effective analgesic. Its transfer to milk is low to nil (Townsend et al., 1984; Weibert et al., 1982).
- Ketorolac is considered an ideal and potent analgesic in breastfeeding mothers. The transfer of ketorolac into milk is extremely low (Wischnik et al., 1989). However, its use in patients with hemorrhage is risky as it inhibits platelet function. Other contraindications are noted in the preceding section on postpartum anesthesia.
- 3. Celecoxib transfer into milk is extraordinarily low (<0.3% of the maternal dose) (Hale, McDonald, & Boger, 2004). Its short-term use is safe.
- 4. Naproxen transfer into milk is low, but gastrointestinal disturbances have been reported in some infants after prolonged therapy. Short-term use (1 week) probably is safe (Fidalgo et al., 1989; Jamali & Stevens, 1983).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

The recommendations were based primarily on a comprehensive review of the existing literature. In cases where the literature does not appear conclusive, recommendations were based on the consensus opinion of the group of experts.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of analgesics and anesthetics in breastfeeding mothers
- Improved quality of care in breastfeeding mothers
- Decreased pain
- Decreased treatment-related side effects and adverse events in the breastfed infant

POTENTIAL HARMS

- Pain that exceeds a woman's ability to cope, or pain magnified by fear and anxiety, may produce suffering in labor. Suffering in labor may lead to dysfunctional labors, poorer psychologic outcomes, and increased risk of postpartum depression, all of which may have a negative effect on breastfeeding.
- Depressed or delayed suckling, which can be caused by medications given to mothers, can lead to delayed or suppressed lactogenesis and risk of excess infant weight loss.
- Treatment-related adverse events

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

A central goal of the Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may impact breastfeeding success. These protocols serve only as guidelines for the care of breastfeeding mothers and infants and do not delineate an exclusive course of treatment or serve as standards of medical care. Variations in treatment may be appropriate according to the needs of an individual patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Montgomery A, Hale TW, Academy of Breastfeeding Medicine Protocol Committee. ABM clinical protocol #15: analgesia and anesthesia for the breastfeeding mother. Breastfeed Med 2006 Winter;1(4):271-7. [50 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

Academy of Breastfeeding Medicine - Professional Association

SOURCE(S) OF FUNDING

Academy of Breastfeeding Medicine

A grant from the Maternal and Child Health Bureau, US Department of Health and Human Services

GUIDELINE COMMITTEE

Academy of Breastfeeding Medicine Protocol Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Contributors: Anne Montgomery, MD, Department of Family Medicine, University of Washington, Seattle, WA; Thomas W. Hale PhD, Texas Tech University School of Medicine, Amarillo, TX (Lead authors)

Committee Members: Caroline J. Chantry, MD, Co-Chairperson; Cynthia R. Howard, MD, MPH, Co-Chairperson; Ruth A. Lawrence, MD; Nancy G. Powers, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

None to report

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Academy of Breastfeeding Medicine Web site</u>.

Print copies: Available from the Academy of Breastfeeding Medicine, 140 Huguenot Street, 3rd floor, New Rochelle, New York 10801.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Procedure for protocol development and approval. Academy of Breastfeeding Medicine. 2007 Mar. 2 p.

Print copies: Available from the Academy of Breastfeeding Medicine, 140 Huguenot Street, 3rd floor, New Rochelle, New York 10801.

A Korean translation of the original guideline document is available from the Academy of Breastfeeding Medicine Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on November 14, 2007. The information was verified by the guideline developer on October 31, 2008.

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